K001120

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MENNEN
MEDICAL LTD.

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Date prepared: 30 March 2000

Topic: **510(k) Safety and Effectiveness Summary as per 21 CFR Section 807.92**
ENVOY Patient Monitor with Neonatal application

Establishment Name, Registration Number and Address

Name:	Mennen Medical Ltd.
Registration Number	9611022
Operator Number:	9011766
Address:	Kiryat Weizmann Science Park Rehovot 76100 Israel Tel: 972-8-938-3030 Fax: 972-8-940-6519
Contact person:	Ken Raichman, Director of Regulatory Affairs

To: Food and Drug Administration
Center for Devices and Radiological Health Document Control Center (HFZ-401)
9200 Corporate Boulevard
Rockville MD, 20850

Attn.: Document Control Clerk

From: Kenneth Raichman
Director of Regulatory Affairs

Product Name

Proprietary: ENVOY
Common: Physiological Patient Monitor
Mennen Medical Part Number: 550-010-017

FDA Classification

Classification Name:	Arrhtymia Detector and Alarm
Classification Number:	21 CFR 870.1025
Classification:	Class III
Product Code:	74 DSI

Performance Standards

None promulgated

Voluntary Standards

AAMI/ANSI ES1 Safe Current Limits for Electro-medical Devices
AAMI/ANSI EC13, Cardiac Monitors, Heart Rate Meters and Alarms
AAMI/ANSI SP-10/A1, Electronic or Automated Sphygmomanometers
IEC 601-1 Medical Electrical Equipment
IEC 601-2-27 Safety of electro-cardiographic monitoring
IEC 601-2-30 Requirements for automatic cycling indirect blood pressure monitoring
IEC 601-2-34 Requirements for Invasive Blood Pressure monitoring equipment

Predicate Devices

MENNEN MEDICAL ENVOY PATIENT MONITOR (K974510 and K983864).
MENNEN MEDICAL MERCURY MONITOR (K940081).

Device Description

ENVOY is a hospital based, multiparameter patient monitor for monitoring physiological patient vital signs.

The **ENVOY patient monitor** system consists of the following components:

Main Processing Unit
Display Unit
Module Rack
Vital Signs Plug-in Modules

ENVOY vital signs modules acquire vital signs data from the patient, and display their waveforms and alarms indications on the ENVOY display unit. Vital signs and waveform information are displayed simultaneously on the ENVOY Display Unit. Up to 8 traces can be displayed at any one time.

The vital signs modules interface with readily available physiologic transducers through electrically isolated patient input connections. After amplification, the signals are digitized, analyzed and displayed. All processing and alarm determination for ECG, Respiration and Invasive Blood Pressure is made using proprietary algorithms and software based on previously marketed Mennen Medical monitoring devices tested against well known and accepted data bases that present representative examples of waveform artifact to be encountered in real case conditions. The SpO2, Non-Invasive Blood Pressure and EtCO2 Modules incorporate software and/or hardware technology developed by vendors whose products are marketed in the USA.

Information from each vital sign is presented in a separate portion of the display. Each vital sign is labeled for identification and numeric value. Displayed Vital sign information can include: Primary Vital Sign Name, Waveform, Vital Sign Numeric Value, Alarm Status Message.

Operation of the ENVOY is accomplished by interaction with front panel controls on the main processor unit. A quick-knob control allows direct interaction with displayed menus for direct parameter selection and setup. Where manual entry of alphanumeric information is required, a menu keyboard menu is display.

ENVOY is a reusable, software driven, patient monitor, intended for use as part of a physiological monitoring system in a hospital environment. As such it is not a life supporting, nor life sustaining device; nor is it implantable and therefore sterility is not a consideration.

ENVOY complies with IEC 601-1 Medical Electrical Equipment, IEC 601-2-27 Safety of Electrocardiographic monitoring, IEC 601-2-30 Requirements for Automatic Cycling Indirect Blood Pressure monitoring, AAMI/ANSI SP-10/A1 Electronic or Automated Sphygmomanometers, IEC 601-2-34 Requirements for Invasive Blood Pressure monitoring, AAMI/ANSI ES1 Safe Current Limits for Electromedical Apparatus, and AAMI/ANSI EC13, Cardiac Monitors, Heart Rate Meters and Alarms. ENVOY is not a kit, does not contain any drug or biological products and is not for prescription use.

ENVOY Intended Use:

ENVOY is intended for use as a multiparameter physiological patient monitoring system.

The ENVOY can monitor ECG/heart rate, two invasive blood pressure channels, two temperature channels, pulse oximetry, respiration, non-invasive blood pressure and EtCO2. This effectively allows the ENVOY to monitor a wide-range of adult, pediatric and neonatal patient conditions, in many different areas of the hospital.

Functions include display of multiparameter waveforms, vital signs, alarm & status messages.

The Mennen Medical ENVOY is intended for sale as a system for monitoring and recording patient information or any in-hospital application requiring patient monitoring. The following are examples of intended clinical applications:

- Critical Care Patients
- Cardiac Stepdown/Telemetry Units
- Emergency Departments
- Intra-operative (Anesthesia) Monitoring
- Post Anesthesia Care

Substantial Equivalency Information:

The following tables summarize data on the Mennen Medical ENVOY patient monitor for adult and pediatric use (K974510 and K983864) and the Mennen Medical MERCURY patient monitor for adult, pediatric and neonatal use (K940081) - both are substantially equivalent devices, available in the U.S. market. The above data is compared to the Mennen Medical ENVOY patient monitor for neonatal use, the subject of this 510(k) submittal.

Displayed Parameters	**Mennen Medical ENVOY Patient Monitor (Adult/Pediatric)**	**Mennen Medical ENVOY Patient Monitor (Neonatal)**
ECG	Yes	Yes
Heart Rate	Yes	Yes
Invasive BP	Yes	Yes
Noninvasive BP	Yes	Yes
Pulse Oximetry	Yes	Yes
Temperature	Yes	Yes
EtCO2	Yes	Yes

Alarm Indications:	**Mennen Medical ENVOY Patient Monitor (Adult/Pediatric)**	**Mennen Medical ENVOY Patient Monitor (Neonatal)**
ECG	Visual & Sound	Visual & Sound
Heart Rate	Visual & Sound	Visual & Sound
Invasive BP	Visual & Sound	Visual & Sound
Noninvasive BP	Visual & Sound	Visual & Sound
Pulse Oximetry	Visual & Sound	Visual & Sound
Temperature	Visual & Sound	Visual & Sound
EtCO2	Visual & Sound	Visual & Sound
Graded according to Severity: audio, visual	YES	YES
Technical Alarms (INOPS)	YES	YES

Alarm Indications cont.:	**Mennen Medical ENVOY Patient Monitor (Adult/Pediatric)**	**Mennen Medical ENVOY Patient Monitor (Neonatal)**
Resetting/Suspending Alarms – silence tone, automatic reactivate after set interval	YES	YES

Measurement Principle	**Mennen Medical ENVOY Patient Monitor (Adult/Pediatric)**	**Mennen Medical ENVOY Patient Monitor (Neonatal)**
Heart Rate	From ECG, Pulse Oxymetry, Blood Pressure	From ECG
Invasive BP	Pressure Transducer	Pressure Transducer
Noninvasive BP	Arm Cuff	Arm Cuff
Pulse Oximetry	Infra-red Sensor	Infra-red Sensor
Temperature	Temp probe	Temp probe
EtCO2	Infra-red Sensor	Infra-red Sensor

Auxiliary Functions	Mennen Medical **ENVOY Patient Monitor (Adult/Pediatric)**	Mennen **Medical ENVOY Patient Monitor (Neonatal)**	Mennen Medical **MERCURY Patient Monitor (Adult/Pediatric/ Neonatal)**
Change ECG Lead Selection	YES	YES	YES
Display of Arrhythmia Information	YES	YES	YES
Change BP Range/Scale	YES	YES	YES
Data Review: Trends	YES	YES	YES
Data Review: Tabular	YES	YES	YES
User defined Configuration Setup	YES	YES	YES

Auxiliary Functions cont.	**Mennen Medical ENVOY Patient Monitor (Adult/Pediatric)**	**Mennen Medical ENVOY Patient Monitor (Neonatal)**	**Mennen Medical MERCURY Patient Monitor (Adult/Pediatric/ Neonatal)**
User defined Default Settings	YES	YES	YES

Displayed Parameters	**Mennen Medical Mercury Patient Monitor** (Adult/Pediatric/Neonatal)	**Mennen Medical ENVOY Patient** Monitor (Neonatal)
Respiration	Yes	Yes
Alarm Indications	**Mennen Medical Mercury Patient Monitor (Adult/Pediatric/Neonatal)**	**Mennen Medical ENVOY Patient Monitor (Neonatal)**
Respiration	Visual & Sound	Visual & Sound
Measurement Principle	**Mennen Medical Mercury Patient Monitor (Adult/Pediatric/Neonatal)**	**Mennen Medical ENVOY Patient Monitor (Neonatal)**
Respiration	From ECG	From ECG

Conclusion of comparison of Technological characteristics:

We consider the Envoy patient monitor with neonatal application to be substantially equivalent to the Mennen Medical Envoy patient monitor for adult and pediatric use and to the Mennen Medical Mercury patient monitor.

Testing

The Envoy patient monitor with neonatal application has been subject to extensive safety and performance testing. Final testing for the system included various performance tests designed to ensure that the device meets all functional requirements and performance specifications. Safety testing, EMC testing and Environmental testing has been performed by third party agencies to ensure that the device complies to applicable industry and safety standards. The Envoy patient monitor with neonatal application has also been clinically tested in a local hospital.

Signature:

Kenneth Raichman,
Director of Regulatory Affairs,
MENNEN MEDICAL LTD.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Kenneth Raichman
Director of Regulatory Affairs
Mennan Medical Ltd.
Kiryat Weizmann Science Park
P.O.B. 102
Rehovot 76100 Israel

Re: K001120
Envoy Patient Monitor with Neonatal monitoring
Regulatory Class: III (three)
Product Code: DSI
Dated: July 30, 2000
Received: August 2, 2000

Dear Mr. Raichman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address: http.//www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

510(k) Number (if known): K001120

Device Name: ENVOY Multiparameter Physiologic Monitor

Indications For Use:

ENVOY is intended for use as a multiparameter physiological patient monitoring system. The ENVOY can monitor EGG/heart rate, two invasive blood pressure channels, two temperature channels, pulse oximetry, respiration, non-invasive blood pressure and EtCO2. This effectively allows the ENVOY to monitor a wide-range of adult, pediatric and neonatal patient conditions, in many different areas of the hospital.

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- Emergency Departments
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- Post Anesthesia Care

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K001120

Prescription Use___ OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)